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TAGS: ECON EINV ETRD JA PGOV SOCI
SUBJECT: JAPAN'S GENERIC DRUG MARKET - SMALL NOW BUT WITH HUGE POTENTIAL

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¶1. (SBU) Summary. With public debt nearly double GDP and upward pressure on national health insurance expenditures due to Japan's aging society, the Ministry of Health, Labor and Welfare (MHLW) hopes to increase generic drugs' market share from 17% to 30% by 2012, saving the healthcare system an estimated $25 billion per year. Consumer and physician resistance to generics, along with the GOJ's desire to protect the domestic branded pharmaceutical industry however, will make realizing this goal an uphill battle. With a market potential of $65 billion in annual sales, foreign and domestic pharmaceutical manufacturers are starting to take notice of generics' potential in Japan, as evidenced by the June 15 takeover of Indian generic drugmaker Ranbaxy Laboratories by Japan's second largest pharmaceutical company, Daiichi Sankyo. End Summary.

¶2. (SBU) Japan's healthcare system is feeling the pressure of demographic and economic challenges (ref). The country's society is aging rapidly with the over 65 demographic projected to grow from 20 percent of the population today to 30 percent by 2025. Moreover, the decline in overall population adds to the burden of those still working to support the growing number of seniors. At the same time, the national health insurance (NHI) system encourages doctors to over-prescribe tests and drugs and allows hospital stays that are six times longer than the OECD average. As a result, Japan's 2006 healthcare expenditures reached JPY32.4 trillion ($324 billion), exceeding nine percent of national income in 2006 for the second year in a row. The National Federation of Health Insurance Societies (Kenporen), comprised of 1,502 organizations insuring 30 million company employees and their dependents, projects its deficit will grow to a record JPY632.2 billion ($6.3 billion) in 2008.

Generic Market Underdeveloped

¶3. (SBU) One factor driving spiraling healthcare costs is Japanese consumers' and doctors' preference for brand name drugs over generics. Currently, generics have a 17% share of

the Japanese market, compared to a 63% share in the U.S, and the generics market is dominated by domestic manufacturers. Israel's Teva Pharmaceutical, the world's leading generic manufacturer which holds an 11.4% share of the total U.S. pharmaceutical market, does virtually no business in Japan.

Profits, Mistrust Dampening Adoption

¶4. (SBU) Several factors drive the preference for branded drugs. The first is profit. Many medical institutions in Japan dispense pharmaceuticals, earning substantial revenues doing so. Even physicians in private practice often have profit-sharing arrangements with nearby independent "mom and pop" pharmacies and thus are reluctant to substitute generics for the more lucrative brand name drug. The four drug wholesalers that dominate Japan's distribution system refuse to stock many generics for the same profit reasons. Consequently, medical institutions or pharmacies that would like to offer generics are often unclear as to where to source the drugs.

¶5. (SBU) The second factor is the Japanese generic manufacturers themselves. Most are small, unsophisticated companies with poor inventory management systems that produce frequent stock outages. Doctors and pharmacists hesitate to prescribe generics for fear the product will not be available. The third factor is Japanese consumers' skepticism of the quality and efficacy of generic drugs versus their branded counterparts. Finally, MHLW regulations mandate a "floor" for generic drug prices so that generics

can only be priced at a 30% discount to branded products. As a result, the "co-pay" differential is minimal causing most consumers to stick with their trusted brand.

MHLW's Five-year Plan

¶6. (SBU) Nonetheless, the GOJ recognizes the need to encourage adoption of generics in the face of spiraling healthcare costs. The MHLW has developed a five-year plan to increase generics' market share to 30% by 2012 which, by some estimates, could save the national healthcare system as much as $25 billion per year. The plan seeks to address many of the concerns outlined above. It requires generic manufacturers to eliminate in-house stock outages by 2009 so that all prescriptions can be promptly filled. It mandates quality testing of each batch of drugs produced and compels manufacturers to make the information available upon request, both over the Internet and through brochures distributed to doctors and pharmacists.

¶7. (SBU) The MHLW has also implemented changes affecting how generics are prescribed and how those prescriptions are filled. The Ministry changed the format of doctors' prescription pads in April 2008 so the doctor must check a box specifying the patient may only be given branded product. If the box is not checked, the pharmacist may give the consumer the option of generic or branded medications. In addition, MHLW instituted a system in which pharmacists are awarded points based on the percentage of prescriptions they fill using generics. The more points earned, the higher the reimbursement. The Ministry also issued guidelines to doctors and hospitals "encouraging" them to promote the use of generics or risk losing insurance reimbursements. Finally, MHLW issued an ordinance requiring all prescriptions for welfare recipients be filled with generic drugs.

A $65 billion market?

¶8. (SBU) Still, many feel the GOJ's efforts fall short. Despite the healthcare system's perilous fiscal situation, MHLW wants to proceed cautiously in promoting generics, according to Hiroshi Mitsuhara, President and CEO of Nihon Chouzai Company, one of Japan's largest drugstore chains. The Ministry fears more aggressive measures may imperil

domestic branded pharmaceutical manufacturers, he said. Regardless of MHLW's and the Japanese public's reticence, generics will inevitably play an increasingly important role in the Japanese healthcare system and could eventually top JPY7 trillion ($65 billion) in sales per year, Mitsuhara predicted. He noted Nihon Chouzai currently stocks over 500 generic products, more than twice the average of other drugstores.

Daiichi Sankyo Buys India's Ranbaxy

¶9. (SBU) Recognizing this market potential, Daiichi Sankyo, Japan's second largest pharmaceutical manufacturer, announced the purchase of India's Ranbaxy Laboratories June 15. The eighth largest pharmaceutical company in the world, Ranbaxy has annual gross sales of JPY180 billion ($1.7 billion) and operates in 49 countries, according to Japanese press reports. Ranbaxy entered the Japanese market in 2002, forming a joint venture with Japanese generic manufacturer Nippon Chemiphai. The company's strategic advantage lies in its ability to use India's low-cost manufacturing base to generate higher profits than its competitors who produce in Japan, according to Satyesh Varhadkar, Ranbaxy's head representative in Japan. The joint venture currently has four products that have been approved by the pharmaceutical and medical devices agency and are currently in market, Varhadkar stated. Nevertheless, Varhadkar believes it will be many

years before generics command a substantial Japanese market share. He lamented the difficulty his and other foreign firms face competing in the Japanese pharmaceutical market and suggested the only way to overcome the significant consumer and structural barriers is to form a joint venture with a domestic entity.

Comment

¶10. (SBU) Persuading brand-obsessed Japanese consumers who will queue up for hours to get the "real thing", whether it be Gucci handbags or Krispy Kreme doughnuts, to switch to generic drugs will likely be an uphill battle. With public debt running about double GDP and upward pressure on medical expenditures due to an aging society, however, the GOJ may be forced to take more aggressive steps to push the use of generics. The MHLW goal to raise generics' share to 30% in the world's second largest pharmaceutical market could be a huge opportunity for U.S. and other generic manufacturers willing to take on the coterie of vested interests that control the prescription drug market in Japan. End comment.

SCHIEFFER